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10/506,756

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Roland Kozlowski

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EXAMINER

GROSS, CHRISTOPHER M

ART UNIT

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**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/506,756	<b>Applicant(s)</b> KOZLOWSKI ET AL.	
	<b>Examiner</b> CHRISTOPHER M. GROSS	<b>Art Unit</b> 1639	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☐ Responsive to communication(s) filed on 09 September 2009.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 8-27 is/are pending in the application.
- 4a) Of the above claim(s) 8-15 and 20 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) 16-19 and 21-27 is/are rejected.
- 7) ☒ Claim(s) 20 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)            | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | Paper No(s)/Mail Date. _____                                      |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>5/22/2009</u> .   | 6) <input type="checkbox"/> Other: _____                          |

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### **DETAILED ACTION**

Responsive to communications entered 9/9/2009. Claims 8-27 are pending. Claims 8-15, 20 are withdrawn. Claims 16-19,21-27 are under consideration.

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 9/9/2009 has been entered.

### ***Priority***

The present application 10/506,756 is the national stage of PCT/GB03/01049, filed 3/13/2003, under 35 U.S.C. 371. This application claims foreign priority to United Kingdom priority document 0205910.3, filed 3/13/2002.

### ***Maintained Claim Rejection(s) - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 16-19,21,27 are rejected under 35 U.S.C. 102(b) as being anticipated by **Wang et al** (1996 JBC 271:28311-28317 – IDS entry 2/22/2006; added to the present 892 to correct the incorrect page nos. in the 5/21/2009 892) as evidenced by Gulbis et al (1999 Cell 97:943-952; of record).

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The claimed subject matter per claim 16 is drawn to an array comprising:

a surface having attached thereto at least one cytosolic accessory protein of a membrane protein selected from ion channels, G protein coupled receptors and transmembrane transporter proteins, wherein said cytosolic accessory protein is free from membrane protein components or other subunits of said ion channel, G protein coupled receptor or transmembrane transporter protein complex.

Claims 17-19,21,27 represent variations thereof.

**Wang et al** teach, throughout the document and especially figure 3 (with additional data disclosed in table I), an array of voltage-gated potassium channel beta 1.3 subunits analyzed with a yeast two hybrid system which shows some beta 1.3 subunits interact with alpha subunits and others do not. Said voltage-gated potassium channel beta 1.3 subunits which do not interact with said alpha subunit provide a surface having attached thereto at least one cytosolic accessory protein of a membrane protein selected from ion channels wherein said cytosolic accessory protein is free from membrane protein components or other subunits of said ion channel, as set forth in claim 16. In accordance with the present specification p 11, lines 15-18

Preferably the protein moieties are **attached to the surface** either directly or **indirectly**. The attachment can be non-specific (e.g. **by physical absorption** onto the surface...

Here, as shown in figure 3 of Wang et al. the voltage-gated potassium channel beta 1.3 subunits are indirectly physically attached to the agar plate inside the yeast cell.

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Said voltage-gated potassium channel beta subunits of Wang et al read on the Kv channel beta 1.3 subunits (elected species) set forth in claims 17,18 & 19 and is an ion channel subunit domain, reading on claim 21.

Evidence provided by Gulbis et al in figure 1 indicates that said Kv channel beta subunits of Wang et al are inherently tetrameric (elected species), reading on claim 27.

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Please note that the above rejection has been modified from the original version to more clearly address applicants' newly amended and/or added claims and/or arguments. In this vein, the examiner agrees that the yeast cell membrane of Wang et al does not constitute a surface, as argued on p 7 of the response but rather the agar plate as clarified above.

#### *Response to Arguments*

In the remarks entered 9/9/2009 applicant argues not all elements are taught.

Applicant's arguments have been fully considered but they are not deemed persuasive for the following reasons.

On p 6 of the response applicant argues that claim 16 requires a surface to which is attached a cytosolic accessory protein which is described in the present specification as: (a) "an array-based method whereby the **in vitro binding of** soluble, functional domains of membrane-bound proteins, such as ion channels...**to arrays of immobilised cytoplasmic accessory proteins** can be characterised in detail" on p 3; (b) "arrays according to the invention can comprise **tagged protein** constructs that are each expressed and immobilized in a functional manner in a spatially defined format" on

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p 9; and (c) the nature of attachment to a surface is further described which refer to non-specific attachment to a surface for example **by physical absorption** or by formation of covalent interactions, or by attachment through a common marker moiety linked to each protein on page 11 lines 14-20. Emphasis added.

(a) With regard to p 3 of the specification it is noted that claim 16 is *not* drawn to in vitro binding of soluble, functional domains of membrane-bound proteins, such as ion channels...to arrays of immobilised cytoplasmic accessory proteins, but rather an array comprising a surface having attached thereto at least one cytosolic accessory protein of a... ion channel... wherein said cytosolic accessory protein is **free** from membrane protein components or other subunits of said ion channel... Emphasis added. In other words, the array-based method described on p 3 of the specification is drawn to directly binding of soluble, functional domains of ion channels to immobilized cytoplasmic accessory proteins whereas claim 16 recites the cytoplasmic accessory proteins do *not* include other parts of the channel. Thus, in response to applicant's argument that the references fail to show certain features of applicant's invention, it is noted that the features upon which applicant relies (i.e., an array comprising soluble, functional domains of membrane-bound proteins, such as ion channels plus their corresponding cytosolic accessory proteins) are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993).

(b) With regard to the tagged proteins recited on p 6 of the specification, in response to applicant's argument that the references fail to show certain features of applicant's invention, it is noted that the features upon which applicant relies (i.e., tagged cytosolic accessory proteins) are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993).

(c) Fully consistent with p 11 of the present specification, as mentioned in the clarified rejection above, figure 3 of Wang et al shows the voltage-gated potassium channel beta 1.3 subunits indirectly attached to the agar plate (surface) and retained there by physical adsorption inside the yeast cell.

On p 8 second full of the remarks entered, applicant argues (a) the yeast cells of Wang et al are not attached to the agar plate but are rather grown there and (b) the beta 1.3 subunit expressed protein in said yeast is not in any meaningful way attached to the yeast cells.

(a) This is not found persuasive because the arguments of counsel cannot take the place of evidence in the record. In re Schulze, 346 F.2d 600, 602, 145 USPQ 716, 718 (CCPA 1965); In re Geisler, 116 F.3d 1465, 43 USPQ2d 1362 (Fed. Cir. 1997) ("An assertion of what seems to follow from common experience is just attorney argument and not the kind of factual evidence that is required to rebut a prima facie case of obviousness.") (see MPEP 2145 I.) In the instant case, Applicant's counsel argues the grown yeast cells of Wang et al figure 3 are not physically adsorbed to the agar,

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however counsel does not provide objective evidence establishing this as a fact. If said yeast cells were not attached in some manner, the assay would be impossible since the yeast colonies would mix together.

(b) With regard the beta 1.3 expressed protein in said yeast is not in any meaningful way attached to the yeast cells, as mentioned above, according to p 11 of the present specification the protein moieties are attached to the surface (agar plate) indirectly (physically entrapped in the yeast cells). It should further be noted that the transitional phrase "comprising" means the claim is open to additional elements, including for instance entire yeast cells.

***Maintained Claim Rejection(s) – 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to



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consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 16-19, 21-27 are rejected under 35 U.S.C. 103(a) as being unpatentable over **Wang et al** (1996 JBC 271:28311-28317 – IDS entry 2/22/2006; added to the present 892 to correct the incorrect page nos. in the 5/21/2009 892) as evidenced by Gulbis et al (1999 Cell 97:943-952; of record) in view of **Charych et al II** (US Patent 7148058; of record) .

**Wang et al** is relied on as above.

Said Kv channel beta 1.3 subunits of Wang et al read on the ion channel of claim 23 (in part).

Wang et al do not teach biotin tagging or immobilization via a common marker, as set forth in claims 22-26.

**Charych et al II** teach, throughout the document and especially the title preparation of protein microarrays on mirrored substrates.

Charych et al II teach in column 6, biotinylated proteins (elected species) may be immobilized thereto said microarray, therein reading on the affinity tagged protein of claims 22,23,24,25 and/or the common marker of claim 26.

It would have been *prima facie* obvious for one of ordinary skill in the art, at the time the claimed invention was made to analyze the Kv channel beta 1.3 subunits of Wang et al by anchoring to the protein microarrays on mirrored substrates in the manner of Charych et al II.

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One of ordinary skill in the art would have been motivated to analyze the Kv channel beta 1.3 subunits of Wang et al by anchoring to the protein microarrays on mirrored substrates in the manner of Charych et al II because the mirrored substrates provide 20-50 x signal amplification, as noted by Charych et al II in column 10 line 50.

One of ordinary skill in the art would have had a reasonable expectation of success in applying the mirrored substrates of Charych et al toward studying the Kv channel subunits of Wang et al because Charych et al state the array is well suited toward studying protein-protein interactions (e.g. the Kv channel alpha subunits of Wang et al) in the abstract.

In conclusion, the claimed invention was within the ordinary skill in the art to make and use at the time the claimed invention was made and was as a whole, prima facie obvious.

#### *Response to Arguments*

In the remarks entered 9/9/2009 applicant argues not all elements are taught.

Applicant's arguments have been fully considered but they are not deemed persuasive for the following reasons.

On p 9 paragraph fourth full paragraph, applicant argues Charych et al II do not teach isolation of membrane bound proteins or cytosolic proteins for use on a microarray.

With regard to cytosolic proteins for use on a microarray, in addition to the sections cited in the above rejection, applicants attention is respectfully invited to

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example 10 where Charych et al II teach glutathione-S-transferase (GST) labeled C. pneumoniae antigens were spotted on an array.

In response to applicant's argument that the references fail to show certain features of applicant's invention, it is noted that the features upon which applicant relies (i.e., membrane bound proteins) are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993).

### ***Claim Objections***

Claim 20 is objected to because of the following informalities: The correct status identifier should be "Withdrawn-Previously Presented". Appropriate correction is required.

This is a RCE of applicant's earlier Application No. 10/506,756. All claims are drawn to the same invention claimed in the earlier application and could have been finally rejected on the grounds and art of record in the next Office action if they had been entered in the earlier application. Accordingly, **THIS ACTION IS MADE FINAL** even though it is a first action in this case. See MPEP § 706.07(b). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within

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TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no, however, event will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to CHRISTOPHER M. GROSS whose telephone number is (571)272-4446. The examiner can normally be reached on M-F 9:30-6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher Low can be reached on 571 272 0951. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Christopher M Gross  
Examiner  
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cg

/ Christopher S. F. Low /  
Supervisory Patent Examiner, Art Unit 1639